REMARKS

I. *Claims 1 to 41 are Pending:*

This continuation application was filed with a preliminary amendment that presented new claims 32 to 41. These claims were not considered in the PTO Action. The PTO PAIR system indicates that claims 32 to 41 were entered on August 27, 2003, albeit as a second set of "claims". It is requested that claims 32 to 41 be examined in the next PTO Action along with claims 1 to 31.

The USPTO Action considers claims 1 to 31 from the original application. The preliminary amendment indicated that these claims were to be cancelled. Given that examination has begun on claims 1 to 31, examination should continue on these claims. The appropriate PTO fees are being paid for claims 1 to 41. Accordingly, the claims pending in this application are claims 1 to 41.

II. *Terminal Disclaimer and Indication of Allowability:*

The obviousness double patenting rejection has been overcome by the enclosed terminal disclaimer.

The indication of allowability of claims 9 to 12 and 14 to 21 is appreciated. These claims have been revised to be placed in independent form or now depend on an independent claim that has been indicated to be allowable.

III. *Obviousness Rejection:*

The rejection of claims 1 to 8, 13 and 22 to 31 as being obvious over Afflerbaugh et al (US 4, 202,764) in view of Gigou (US 3,926,797) is traversed.

Afflerbaugh et al and Gigou do not disclose the steps of measuring an osmotic pressure difference and adjusting the filtrate rate based on the measured pressure difference. Independent claims 1, 13 and 22 have been amended to make clear that the osmotic pressure difference is between "blood" and a filtrate. These amendments more clear distinguish Gigou which refers to osmotic pressure varying between a filtrate and a "purification liquid of [a] dialysis bath." Gigou, col. 4, lns. 3-23. Gigou does not disclose measuring osmotic pressure. Independent claim 32 already requires "a pressure sensor measuring a pressure difference between the filtrate chambers and the blood chamber." Similarly, independent claim 33 requires "a filtrate chamber and a permeable membrane separating the blood and filtrate chambers" and "measuring a pressure difference across the permeable membrane to measure an osmotic pressure level". Accordingly, all independent claims require a pressure difference to be measured across a blood/filtrate membrane. This feature is not disclosed in Afflerbaugh et al or Gigou et al..

A. Afflerbaugh et al Teaches A Predetermined Filtrate Rate To Determine A Transmembrane Pressure – In Contrast To Using Osmotic Pressure To Control A Filtrate Rate

The filtrate flow rate in the Afflerbaugh dialysis system is set at a "predetermined rate" and controlled by an ultrafiltrate pump 38. Afflerbaugh et al, col. 4, lns. 64-66. ("The ultrafiltrate pump 38 is activated and adjusted until a desired or predetermined ultrafiltration rate is achieved."). The Afflerbaugh et al filtrate rate is selected. The filtrate rate is used to control the transmembrane pressure which has been previously

determined by a calibration procedure.. The filtrate rate is not dependent on osmotic pressure but is controlled based upon a known required transmembrane pressure.

Afflerbaugh et al teaches measuring "transmembrane pressure" which is different from osmotic pressure. Transmembrane pressure in Afflerbaugh is a measurement of the pressure required across the filter membrane to generate a predetermine flow of liquid (ultrafiltrate). Osmotic pressure is the pressure generated by differences in liquid constituent concentrations across a membrane and is not a function of flow rate. There is no osmotic pressure sensor disclosed or suggested in Afflerbaugh et al. There is no teaching in Afflerbaugh et al of a separate osmotic pressure measurement device that has a blood chamber and a filtrate chamber.

Afflerbaugh et al teaches measuring pressure in a dialyzer. Afflerbaugh et al teaches away from measuring osmotic pressure in a device separate from a filter or dialyzer, is the pressure difference between the blood pressure on one side of a membrane and the dialysis solution or filtrate pressure on the other side of the membrane. Afflerbaugh, col. 1, lns. 43-52. Afflerbaugh (see col. 2 lines 40 to 46) discloses a method to calibrate transmembrane pressure to estimate a resultant ultrafiltration (UF) rate. The Afflerbaugh system uses a flow meter to determine the correlation with transmembrane pressure. *See e.g.*, Afflerbaugh at col. 4 lines 40 to 68 and col. 5 lines 1 to 26. The transmembrane pressure is measured while blood flows through the dialyzer. Afflerbaugh, col. 4, lns. 56-58. There is no teaching or suggestion in Afflerbaugh et al of

measuring osmotic pressure across the dialyzer membrane of measuring osmotic pressure in a device separate from the dialyzer membrane.

B. Gigou Does Not Teach Measuring An Osmotic Pressure Across a Blood/Filtrate Membrane

Gigou does not teach measuring an osmotic pressure difference between "blood" and filtrate, as is does in the claimed invention. Gigou discloses a system in which osmotic pressure varies with respect to the dialysate in contact with ultrafiltrate across a membrane.

Gigou et al does not refer to an osmotic pressure between a liquid and blood, which is the subject of the rejected claims.

Figures from Gigou el al are reproduced below.

FIG.1.

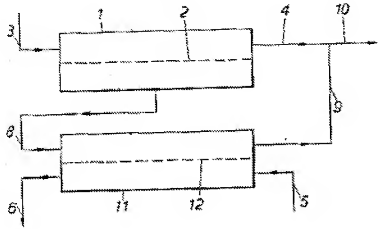
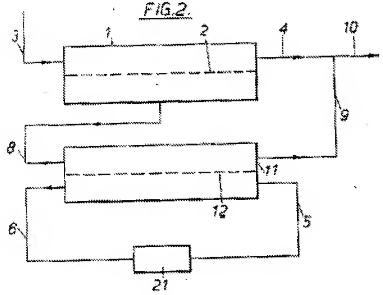


FIG.2.



In Figures 1 and 2 of Gigou et al, blood flows through pipelines 3 and 4 and passes through an ultrafiltration cell 1 where ultrafiltrate is removed from the blood and flows through pipeline 8. Osmotic pressure is not measured in cell 1 and the osmotic pressure is not measured with respect to the blood flowing through lines 3 and 4. The ultrafiltrate in pipeline 8 enters a dialyzer 11 that has an ionic membrane 12. The osmotic pressure

between the ultrafiltrate and dialysis purification fluid across this membrane is varies. The purified ultrafiltrate is added via pipeline 9 to the blood being infused through pipeline 4.

Gigou does not describe the relationship between osmotic pressure, blood volume changes and hypotension. Because Gigou uses dialysate to generate an osmotic, the resultant osmotic pressure is not related to the patients blood volume or potential for hypotension. Gigou also states that osmotic pressure which may be adjusted with adding constituents such as sugars to the dialysate which will vary the osmotic pressure independent of blood volume changes.

The combination of Gigou et al and Afflerbaugh et al would not have rendered obvious the claimed invention. These references do not suggest controlling a filtrate removal rate from blood or using osmotic pressure to provide such control. Afflerbaugh et al uses a predetermined filtration rate and teaches away from controlling the filtration rate. Further, Afflerbaugh et al relies on transmembrane pressure and teaches away from osmotic pressure. Gigou et al does not suggest removing a volume of filtrate from the blood, but rather suggests purifying filtrate and reintroducing the filtrate to the blood. Gigou et al also teaches using the osmotic pressure of a purification liquid and the osmotic pressure of an ultrafiltrate to control the purification of the ultrafiltrate. Gigou et al does not suggest using an osmotic pressure of the blood or a difference between the osmotic pressure of the blood and ultrafiltrate to determine an flow rate of the ultrafiltrate. Accordingly, the claimed invention would not have been obvious.

All claims are in good condition for allowance. If any small matter remains outstanding, the Examiner is requested to telephone applicants' attorney. Prompt reconsideration and allowance of this application is requested.

The Commissioner is hereby authorized to charge any deficiency, or credit any overpayment, in the fee(s) filed, or asserted to be filed, or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Account No. 14-1140.

Respectfully submitted,

NIXON & VANDERHYE P.C.

By: /Jeff Nelson/
Jeffry H. Nelson
Reg. No. 30,481

JHN:glf
1100 North Glebe Road, 8th Floor
Arlington, VA 22201-4714
Telephone: (703) 816-4000
Facsimile: (703) 816-4100